

REMARKS

In the Office Action, Claims 1, 2, 5, 10, and 12 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent Number 5,500,416 to Miyazawa et al. (“Miyazawa”). Claims 1 – 6 and 8 – 12 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by PCT Publication WO 2004/015124 to Menart et al. (“Menart ’124”). Finally, Claim 7 was rejected under 35 U.S.C. § 103(a) as allegedly obvious from Menart ’124 combined with Vuillard et al., Biochemistry Journal 305: 337 – 343 (1995) (“Vuillard”).

By the present amendment, the subject matter of Claim 5, which is now cancelled, is moved into Claim 1. Thus, Claim 1, as amended, is now essentially prior Claim 5, also calling for a pharmaceutical composition suitable for parenteral administration. Since Claim 1 previously was directed to a “pharmaceutical formulation” and the reference to a parenterally administratable form thereof merely designates a subcategory of a type or form of the claimed pharmaceutical formulation, the requested amendment to Claim 1 in this regard should be entered. Furthermore, since Claim 5 has already been examined on the merits, the amendment to Claim 1 incorporating Claim 5 should also be permitted. However, if the Examiner disagrees and believes there would be valid grounds to properly refuse entry of all or part of the requested amendments to Claim 1, Applicants urge the Examiner to first contact the undersigned in an effort to resolve any misunderstanding in this regard.

In view of the amendment to Claim 1 and cancellation of Claim 5, Claims 1 – 4 and 6 – 12 are the currently pending claims. Claim 1 is the only independent claim currently under examination.

Each of the above-mentioned rejections is respectfully traversed. Favorable reconsideration is requested in view of the above amendments and following remarks.

I. Claims 1, 2, 5, 10, and 12 Patentably Distinguishes Over Miyazawa.

The Examiner continues to assert that Claims 1, 2, 5, 10, and 12 are anticipated by Miyazawa. This assertion is not understood. The present claims require, among other things, a pharmaceutical composition which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine, or “NDSB.” In this regard, it is undisputed that some sulfobetaines are characterized in the art as “non-detergent” sulfobetaines or NDSBs. Non-detergent sulfobetaines

or NDSBs do not exhibit surfactant or detergent properties because they do not form micelles in water. On the other hand, “ordinary” sulfobetaines exhibit surfactant properties.

Accordingly, Applicants’ claims specify, among other things, a pharmaceutical composition containing a sulfobetaine known in the art as an NDSB. Again, an NDSB is not referred to as a sulfobetaine because it does not tend to form micelles in water. An NDSB is therefore distinguished from an ordinary sulfobetaine, which exhibits surfactant properties.

Miyazawa mentions the word “sulfobetaine” at column 3, line 31; column 4, line 42, in claims 6 – 9, and in other places. But Miyazawa never comments about the nature or properties of the “sulfobetaine.” The term is unqualified.

As noted above, it is undisputed that, in the vernacular of the trade, ordinary sulfobetaine is understood to be a sulfobetaine that exhibits surfactant or detergent properties. The Examiner has the burden to show that the subject matter of Applicants’ claim is anticipated or would have been obvious from the prior art. However, the Examiner has failed to meet her burden in this regard. The Examiner has not shown that a person of skill would interpret the many “unqualified” references to sulfobetaine in Miyazawa to be anything other than references to ordinary detergent sulfobetaine. Of course, this is not the non-detergent sulfobetaine or “NDSB” called for in Claim 1. Hence, Miyazawa cannot lawfully be said to anticipate Claim 1.

A second reason Miyazawa cannot lawfully be said to anticipate Claim 1 is that the claim now also requires the NDSB to be a quaternary ammonium salt having a nitrogen atom and four groups R1, R2, R3, and R4 – SO₃⁻ bound to the nitrogen atom, wherein R1, R2 and R3, which can be the same and/or different, are selected from the group consisting of one or more of methyl, ethyl, propyl, butyl, pentyl, hexyl and derivatives thereof, and R4 is (CH₂)_n, wherein n is between 1 and 6.

Again, Miyazawa fails to elucidate the structure or properties of the sulfobetaine repeatedly mentioned therein without qualification. Miyazawa certainly fails to disclose or suggest a non-detergent sulfobetaine or “NDSB” having the special properties or structure called for in amended Claim 1. Nor is it said that Miyazawa shows a sulfobetaine according to the structure set forth in former Claim 5, now in Claim 1.

Accordingly, for at least the reasons discussed above, no lawful basis has been established to support the assertion that Miyazawa anticipates all the limitations of Claim 1 under Section 102 of the Patent Act. It is therefore respectfully submitted that the anticipation rejection

of Claim 1 and of its dependent claims based upon Miyazawa cannot stand, and must be withdrawn.

II. Claims 1 – 6 and 8 – 12 Patentably Distinguishes Over Menart.

The Examiner further asserts argues that the subject matter of Claims 1 – 6 and 8 – 12 are anticipated by Menart. This rejection is also unfounded.

Claim 1 calls for, among other things, a “pharmaceutical composition” suitable for parenteral administration, and which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine or “NDSB”. In other words, the NDSB is a component of the claimed dosage form of a “pharmaceutical composition,” now also said to be formulated for administration to a subject parentally. Menart does not show this.

In Menart, an NDSB compound is mentioned only for use as a solvent for dissolving so-called “non-classical” inclusion bodies found in cell residue of organisms such as E. coli, fermented in a certain way so as to induce formation of the desired inclusion bodies. This disclosure of NDSB as a protein solvent in fermentation residue is hardly a disclosure of a “pharmaceutical composition,” much less a disclosure of a pharmaceutical formulation for parenteral administration to a subject.

Since Menart fails to disclose at least the aforementioned limitations of Claim 1, it is respectfully submitted that the anticipation rejection of Claim 1 and of its dependent claims based upon Miyazawa is not well founded, and must be withdrawn.

III. Claim 7 Patentably Distinguishes Over Menart and Vuillard.

The Examiner contends that Claim 7 would have been obvious over Menart taken in combination with Vuillard. Claim 7, however, depends from Claim 1, and thus necessarily incorporates all of the limitations of Claim 1. In particular, Claim 7 calls for, among other things, a “pharmaceutical composition” which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine or “NDSB” in a formulation suitable for parenteral administration to subject. Menart plainly does not show this. Vuillard also fails to show this, or anything remotely similar to this.

Vuillard mentions use of NDSB compounds in a context very far away from that of the current claims. Vuillard describes what are said to be the investigatory effects of NDSB

compounds on the “renaturation yield” and other aspects of protein renaturation for processes of protein manufacture and collection, harvesting, and the like.

As with Menart, this suggests nothing toward the use of NDSB in a “pharmaceutical formulation” in accordance with the subject matter of Applicants’ claims. Neither Vuillard nor Menart has any reasonable connection to the subject of the present invention, and they certainly could not be fairly said to have suggested the use of an NDSB compound as claimed in a pharmaceutical formulation, much less one suitable for parenteral administration.

Neither Menart or Vuillard discloses or suggests Applicants’ claimed invention. Nor would any combination of these references have suggested the invention as claimed to a person of ordinary skill in the art. Accordingly, it is respectfully submitted that the Examiner’s purported combination of these references cannot lawfully be said to render the subject matter of Claim 7 obvious according to a proper application of Section 103. Hence, the obviousness rejections are not well founded, and should be withdrawn.

IV. The Withdrawn Claims are Cancelled.

Finally, it is noted that Claims 14 – 16, which have previously been made subject to restriction, have been cancelled without prejudice from the current application. Applicants nonetheless wish to make of record that they expressly reserve the right to prosecute the subject matter of these claims in one or more copending divisional applications.

In light of the foregoing, the present amendment is believed to place the application in a condition for allowance and entry of the foregoing amendments and allowance of the claims is respectfully solicited.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. **12-2355**.

Respectfully submitted,

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